

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP,)	
ASTRAZENECA UK LIMITED,)	
IPR PHARMACEUTICALS, INC., and)	
SHIONOGI SEIYAKU KABUSHIKI KAISHA,)	
)	
Plaintiffs,)	C.A. No. 07-809-JJF
)	
v.)	
)	
APOTEX INC., and APOTEX CORP.,)	
)	
Defendants.)	

**APOTEX CORP.'S REPLY BRIEF IN
SUPPORT OF ITS MOTION TO DISMISS**

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I. INTRODUCTION

Apotex Corp. has moved to dismiss the complaint against it on three separate grounds: (1) Apotex Corp. is not a proper defendant under Count I because it is not the ANDA applicant; (2) Count II fails to state a claim for declaratory relief because Defendants have not actually made, used or sold the allegedly infringing drug products in the United States and their conduct is otherwise protected under the safe harbor provisions of the Hatch-Waxman Act; and (3) the complaint must be dismissed for failure to join an indispensable party in the event Apotex Inc. is dismissed from the suit for lack of personal jurisdiction. As explained below, Plaintiffs AstraZeneca Pharmaceuticals, LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi Seiyaku Kabushiki Kaisha (“Plaintiffs”) have failed to overcome Apotex Corp.’s arguments as to why its motion to dismiss should be granted.

II. ARGUMENT

A. Apotex Corp. Cannot Be Sued Under Section 271(e)(2)

Apotex Corp. claims that that Count I should be dismissed against it under Rule 12(b)(6) because under the statute that defines the cause of action alleged in Count I (patent infringement under 35 U.S.C. § 271(e)(2)), a claim for patent infringement based on the filing of an ANDA may only be brought against the actual ANDA applicant, and it was Apotex Inc. that was the ANDA Applicant—not Apotex Corp.

In response, Plaintiffs contend that Apotex Corp. is liable under Section 271(e)(2) because it “participated” in the submission of the ANDA with the “purpose” of “selling” generic rosuvastatin calcium and because Apotex Corp. will sell the drug in the U.S. if the ANDA is approved. (Response pp. 3-4.) However, Plaintiffs’ argument is not supported by the plain language of the statute, which states:

[i]t shall be an act of infringement to *submit* . . . an [ANDA] application under Section 505(j) of the Federal Food, Drug and Cosmetic Act . . . if the *purpose of such submission* is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (emphasis added). The language of the statute is clear—the act of infringement is the *submission* of the ANDA application for the purpose of obtaining approval to later manufacture, use or sell a drug claimed in a patent, and this is exactly what Apotex Inc. did. The fact that Apotex Corp. may, at some point in the future, be involved in selling generic Crestor manufactured by Apotex Inc. if the ANDA is successful, does not subject Apotex Corp. to patent infringement liability so long as it is not the actual ANDA applicant.

In connection with this argument, Plaintiffs contend that the definition of “applicant” includes multiple applicants in addition to the ANDA owner. (Plaintiff’s Brief p. 4.) However, the C.F.R. section relied on by Plaintiffs limits the definition of “applicant” to “any person who *submits an application* or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug *and any person who owns an approved application* or abbreviated application.” 21 C.F.R. § 314.4. Of course, as shown in Confidential Exhibit A to Apotex Corp.’s Moving Brief, the ANDA form at issue here clearly identifies “Apotex Inc.” as the “applicant” and lists the “applicant’s” address as Apotex Inc.’s address in Canada. “Apotex Corp.,” on the other hand, is merely identified as Apotex Inc.’s “Responsible Official or Agent.” (Ex. A to Moving Brief.) Since Apotex Corp. is not the “person who submit[ted] the application” and does not “own an approved application,” Section 314.3 does not support Plaintiffs’ argument, but in fact buttresses Apotex Corp.’s position that it is not a proper defendant here.

Plaintiffs also rely on two cases from other district courts to support their claim that Apotex Corp., as the authorized U.S. agent who signed the ANDA on behalf of Apotex Inc., is a proper party defendant. However, these cases should not be followed because they ignore the plain language of the statute and contain faulty analysis.

In the first case cited by Plaintiffs, *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484 (E.D. Va. 2005), an India-based generic manufacturer (Lupin) submitted an ANDA to make a generic version of plaintiff's drug and its U.S. subsidiary signed the ANDA as Lupin's U.S. agent. The U.S. agent moved to be dismissed from the case because its only role in connection with the ANDA was signing the application as Lupin's U.S. agent. The Court denied the motion, but in so doing, gave undue deference to facts that had no bearing on the specific language of 35 U.S.C. § 271(e)(2). For instance, the court relied heavily on the fact that the U.S. company was a wholly-owned subsidiary of the ANDA applicant; that it marketed the applicant's products in the United States; and further considered the definition of "agent" under the Second Restatement. 403 F. Supp. 2d at 492-493. However, this reasoning gives improper weight to conduct that does not and cannot form the basis for an infringement claim under 35 U.S.C. § 271(e)(2).

As stated above, the "act of infringement" under Section 271(e)(2) is the *submission* of the ANDA—not an entity's status as a subsidiary of another entity or the fact that an entity may someday distribute the generic drug that is the subject of the ANDA. Indeed, the Supreme Court has stated that Section 271(e)(2) created a "highly artificial act of infringement *that consists of submitting an ANDA* or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661,

678 (1990) (emphasis added). Because Count I alleges a very specific and “artificial” statutorily-created cause of action, this Court should consider the artificial infringing act itself—the filing of the specific ANDA in this case, which was filed by Apotex Inc. and only signed by Apotex Corp. as its authorized U.S. agent to satisfy the applicable regulations. The Court should not consider the corporate relationship between Apotex Inc. and Apotex Corp. (which is not a parent-subsidary relationship in any event), or the fact that Apotex Corp. may some day distribute generic Crestor manufactured by Apotex Inc. if the ANDA is approved, or the general common-law principles of agency, because this relationship and these activities have no bearing on the artificial act of infringement that is the basis for the infringement claim under Section 271(e)(2) in the first place. As recognized by the Federal Circuit, Section 271(e)(2) “explicitly defines the act of infringement as the filing of the ANDA.” *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). Since Apotex Inc. alone is the only identified applicant, Apotex Inc. alone should be the only defendant to a Section 271(e)(2) claim.

The second case relied on by Plaintiffs, *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303 (D. Md. 2007), is similarly inapplicable. In that case, which involved the same defendant and similar fact pattern as in *Aventis*, the court also ruled that the U.S. subsidiary of an India company could be liable for infringement under Section 271(e)(2) based on the subsidiary’s signing the ANDA as the agent of the overseas company, and the court denied the U.S. subsidiary’s motion to dismiss largely relying upon the opinion in *Aventis*. The court concluded that “when a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. and is actively involved in the ANDA process, the subsidiary also ‘submits’ an ANDA application.” 505 F. Supp. 2d at 307. The ruling in *Wyeth* was in error for the same reasons as *Aventis*—to the extent that the ruling was based on the fact that it was a

subsidiary and distributed product for the foreign parent (which activities had nothing to do with the ANDA in question), such activities should not have been the basis for alleging liability under Section 271(e)(2). Perhaps more importantly, to the extent that there was evidence that U.S. subsidiary was “actively involved in the ANDA process” in *Wyeth*, the case is distinguishable from the case at bar because there is no allegation that Apotex Corp. was “actively involved” in the ANDA process here. Instead, Apotex Corp. was merely the U.S. entity who signed the papers on behalf of the Canadian applicant (Apotex Inc.) as required by 21 C.F.R. §§’s 314.52(c)(7)(c) and 314.50(a)(5).

The better-reasoned authorities cited in Apotex Corp.’s moving brief carefully apply the language of the statute, and should govern the outcome of this motion. Indeed, Plaintiffs do not effectively distinguish the facts in the *Geneva* and *Pentech* cases relied upon by Apotex Corp., in which the parties that were deemed not to be proper defendants under Section 271(e)(2) were much more involved in the ANDA process than was Apotex Corp. here. For instance, in *Smithkline Beecham Corp. v. Geneva Pharmaceuticals Inc.*, 287 F. Supp. 2d 576 (E.D. Pa. 2002), the party who plaintiff attempted to name as a defendant in its 271(e)(2) claim (“Sumika”) manufactured and provided the actual compound at issue in the ANDA and provided “technical assistance that formed the basis of” the ANDA filer’s ANDA for commercial marketing of the generic drug in question. 287 F. Supp. 2d at 579-80. In further support of the ANDA, Sumika filed a “Drug Master File” with the FDA for the compound in question, on which the FDA was authorized to rely in support of the ANDA. Finally, Sumika would “make and sell” the active ingredient for the generic product if the ANDAs were approved. *Id.* Even so, the court ruled that Sumika was not a proper defendant because “[b]y its terms, the Act limits liability for direct infringement to the party submitting the ANDA.” *Geneva*, 287 F. Supp. 2d at 584. If these

activities were not enough to support a Section 271(e)(2) claim against Sumika in *Geneva*, then Apotex Corp.'s signing of the ANDA as required by the statute for ministerial purposes should not be enough either, even if Apotex Corp. may someday distribute generic rosuvastatin calcium in the United States.

The *Pentech* case is similarly instructive. In that case, the plaintiff patent owner moved for leave to amend its complaint to add a claim under 271(e)(2)(a) against a manufacturer ("Asahi") of the active ingredient of the drug in question. The court denied the motion because Asahi was not the ANDA filer:

Asahi cannot be held liable as a direct infringer under section 271(e)(2)(a) because Asahi did not submit the ANDA at issue. . . . Smithkline's interpretation of section 271(e)(2)(a) as allowing a person other than the ANDA filer to be held liable for direct infringement under that section is not supported by the plain language of the statute. The plain language of the statute controls.

Smithkline Beecham Corp. v. Pentech Pharms., Inc., No. 00 C 2855, 2001 U.S. Dist. LEXIS 1935 at *8-*9 (N.D. Ill. Feb. 16, 2001). Like the facts in *Geneva*, Asahi was the supplier of the active ingredient of the drug in question in *Pentech*; Asahi's Drug Master File was relied on in connection with the ANDA, and Asahi would have been the ANDA filer's solely approved manufacturer of the active ingredient in the proposed generic product if it received FDA approval. If a party so intimately involved with the ANDA process and a party who stood to gain if the ANDA application was successful was not liable under 271(e)(2)(a) because it was not the ANDA filer, neither should Apotex Corp. be liable merely because it counter-signed the application as the U.S. Agent of Apotex Inc. or because Apotex Corp. could end up distributing the drug in the U.S. in the event FDA approval is obtained. As stated by the court in *Pentech*, "the plain language of the statute controls." *Id.*

B. There Is No Case Or Controversy Under Count II

In its moving brief, Apotex asserted that Count II of the Complaint should be dismissed as to both Defendants under Rule 12(b)(1) because there is no case or controversy between Plaintiffs and Defendants under 35 U.S.C. § 271(a), which requires an accused to make, use, offer to sell, sell, or import infringing inventions, and there is no allegation that Defendants have actually made, used, sold, or imported any generic Crestor tablets.

In response, Plaintiffs cite a number of cases to support their assertion that facts which form the basis for their Section 271(e)(2) claim can be considered in deciding whether a case or controversy exists under Section 271(a). However, none of the cases cited by Plaintiffs involved the unique fact pattern present in the case at bar—a plaintiff that alleges infringement under Section 271(a) based solely on the submission of an ANDA that has also triggered the “artificial” infringement provisions of 35 U.S.C. § 271(e)(2). For this simple reason, none of the cases cited by Plaintiffs provides support for Plaintiffs’ claim under Section 271(a).

For instance, in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), relied on by Plaintiffs, the case did not address a party’s ability to bring a Section 271(a) infringement claim at the same time as a Section 271(e)(2) claim. Instead, the plaintiff in that case attempted to bring an infringement claim under 271(g) (precluding the importation of materials made by a patented process), since the plaintiff was precluded from bringing an infringement claim under 271(e) because the patent claimed a *method* for making drugs. (Section 271(e)(2) “does not provide jurisdiction to hear infringement cases regarding claims directed to methods for making drugs.” 110 F.3d at 1570). Therefore, Plaintiffs’ reliance on *Glaxo* to support its claim under 271(a) is inappropriate, because that case did not address the policy conflict of bringing a claim

under 271(a) based on the same facts that support a claim under Section 271(e)(2), as explained in Apotex Corp.'s moving brief.

Amgen v. Hoffman-Laroche Ltd., 456 F. Supp. 2d 267 (D. Mass. 2006), also relied on by Plaintiffs, is similarly distinguishable. First, that case did not even involve a claim of infringement based on the filing of an ANDA application. Instead, the defendant had submitted a Biologic License Application with the FDA to sell pharmaceutical compositions that plaintiff claimed would infringe its patents. Defendant had further hired key management and other personnel to market and sell the product once FDA approval was received, retained outside consultants and vendors to sell the product; contacted potential customers; and completed construction of a new facility in Germany to manufacture the composition. 456 F. Supp. 2d at 272. The court found that even though some of these activities were protected under the safe harbor provisions of 271(e)(1), not all of these activities were protected. The court ruled that the allegations stated a claim for relief for current infringement (based on importing material into the United States that may constitute infringement under 271(a)) and also stated a claim for threatened infringement in the future, based on acts that "in no way implicate the section 271(e)(1) exemption." 456 F. Supp. 2d at 277. The *Amgen* court noted that it could exercise declaratory judgment jurisdiction because the defendant was "operating outside the safe harbor exemption" of Section 271(e)(1). 456 F. Supp. 2d at 279. Of course, in the case at bar, Apotex Inc. is operating completely within the "safe harbor" exemption of Section 271(e)(1) exemption, so *Amgen* does justify Plaintiffs' additional claim under Section 271(a) here.

In fact, the court in *Amgen* distinguished that case from its earlier decision in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, where it was "concerned with invading the protective safe harbor." *Id.* In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998),

the court concluded that where, as here, the parties' conduct fell within the safe harbor provisions of Section 271(e), it would not entertain a claim for declaratory judgment based on possible future infringement:

[S]ubjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption. The purpose of the clinical trials exemption is to expedite the arrival of generic drugs on the market upon the expiration of a patent. . . . Declaratory judgment actions have the potential to discourage and hamper the very efforts that Congress sought to stimulate, by subjecting potential competitors to the same burdensome litigation that Congress sought to eliminate. . . . Because the Defendants in this case will violate the law only if they step outside the protective safe harbor that Congress has created, this Court is hesitant to invade that harbor under the auspices of declaratory relief.

3 F. Supp. 2d at 112-113. The same is true in the case at bar. Section 271(e)(1) of the Hatch-Waxman Act was drafted to give safe harbor to the activities related to submitting an ANDA, and any suit for infringement under the statute should be limited to the provisions under 271(e)(2). To permit Plaintiffs to also sue under Section 271(a) based on a fear of infringement at some point in the future would defeat the purpose of the safe harbor provisions and should not be allowed.

Amgen, Inc. v. International Trade Commission, No. 2007-1014, 2008 U.S. App. LEXIS 5751 (Fed. Cir. March 19, 2008), also relied on by Plaintiffs, does not support Plaintiffs' claim that it can bring a declaratory judgment suit for future infringement under Section 271(a) here. That case did not even involve an ANDA, but a Section 337 claim before the ITC in an effort to keep products made with an allegedly infringing method out of the United States. In response to the claim that the products were protected under the safe harbor provisions of the Hatch-Waxman Act, the Court held that under the safe harbor exemption of 35 U.S.C. § 271(e)(1), the imported drug product was not subject to exclusion from the U.S. based on plaintiff's infringement claims, but that defendant's use of imported product not related to obtaining FDA

approval was not shielded by the exemption. *Id.* at *24. As with the *Hoffman-Larouche* case, the suit was permitted to go forward based on conduct that was not protected by the safe harbor provisions. Because the alleged conduct of defendants in the case at bar is not outside the safe harbor provisions of Section 271(e)(1), the *Amgen v. ITC* case does not support plaintiffs' theory that they can bring suit under 271(a) for the same conduct that is shielded under 271(e)(1).

Plaintiffs' various other arguments as to why the Court should exercise jurisdiction over Plaintiffs' Section 271(a) claim are also without merit. First, Plaintiffs claim that they should be able to maintain the claim because Apotex will "enter the market as soon as legally possible." (Plaintiff's Response pp. 8-9.) This, however, is beside the point. The fact that Apotex will potentially enter the market as soon as it receives FDA approval does not create a case or controversy under Section 271(a) where, as here, Plaintiffs have already brought a claim under Section 271(e)(2). Indeed, if it becomes "legally possible" for Apotex to enter the market, this will most likely be because Apotex has established the invalidity of Plaintiffs' patent, so Plaintiffs would no longer have a valid claim against Apotex at that point in time in any event.¹

Plaintiffs further claim that their Section 271(a) claim is appropriate because FDA approval is not required in order for the court to exercise jurisdiction, and that the filing of an ANDA itself can create an actual case or controversy. (Plaintiffs' Response, p. 9.) This argument, however, misses the point, because Apotex does not claim that a drug must obtain

¹ The cases cited by Plaintiffs in this regard are also inapposite. *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006 (N.D. Ill. 2001) was not a case where the plaintiff sued for infringement under Section 271(e)(2) based on infringement of a patent filed in the Orange Book under the Hatch Waxman Act and there was no claim that the activity that formed the basis of the infringement claim came within the safe harbor provisions of Section 271(e)(1). Neither did *Abbott Labs. and Central Glass Co. Ltd. v. Baxter Healthcare Corp.*, No. 04-C-836, 2007 U.S. Dist. LEXIS 76449 (N.D. Ill. Aug. 16, 2004) involve a simultaneous claim for infringement under Sections 271(a) and 271(e)(2), so the policy considerations identified in Apotex Corp.'s moving brief were not in play in that case.

FDA approval before a case or controversy is presented. Neither does Apotex propose a “*per se* rule for ANDA cases that the 30-month stay of FDA approval precludes declaratory judgment jurisdiction.” (Plaintiff’s Response pp. 9-10.). The point is that under the facts of this particular case, where a 30-month stay has been entered preventing the FDA from approving Apotex Inc.’s ANDA, and where Plaintiffs’ claim under Section 271(e)(2) will, as a practical matter, resolve any issue surrounding possible future infringement under Section 271(a), the facts alleged, “under all the circumstances,” do not present a controversy of “sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007).²

Plaintiffs claim that their suit under Section 271(a) is permissible because the “Hatch-Waxman Act expressly contemplated that an ANDA applicant may be sued upon submitting an ANDA that certifies the applicant’s intention to market the drug product before patent expiration.” (Response Brief p. 13.) This argument should be rejected, however, because the authorities cited were talking of infringement suits under *Section 271(e)(2)*, not suits under Section 271(a). Apotex does not deny Plaintiffs’ right to bring a suit under Section 271(e)(2) once the requirements of the statute are met.

Plaintiffs do not adequately distinguish the authorities cited in Apotex Corp.’s moving brief, which discuss the reasons for the safe harbor provisions of Hatch-Waxman. Even if the underlying facts in the authorities cited by Apotex are not identical to the facts in this case, the policy arguments articulated in the authorities cited by Apotex are equally applicable in this case, and Plaintiffs’ should not be permitted to override the safe harbor protections of Hatch-Waxman

² Again, none of the cases cited in connection with this point involved a situation where a party was able to bring concurrent claims under Section 271(a) and Section 271(e)(2). See *Glaxo v. Novopharm*, 110 F.3d at 1571; *Glaxo v. Apotex*, 130 F. Supp. 2d at 1008; and *Takeda Chem. Indus. Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004).

by bringing a Section 271(a) claim against Apotex based on its conduct in preparing an abbreviated new drug application.

Finally, Plaintiffs' claim that they should be permitted to bring a Section 271(a) claim against Apotex in order to obtain additional remedies that are not available under Section 271(e) is also without merit. There are no allegations in the complaint that either defendant will be involved in "active inducement" of importation of allegedly infringing product into the United States, or that Apotex may "enter into an agreement to market rosuvastatin calcium that is the subject of some other entity's ANDA." (Response Brief p. 15.) Such pure speculation cannot support Plaintiff's claim for declaratory judgment under Section 271(a).

At the very least, this Court should exercise its considerable discretion and decline to exercise jurisdiction over Count II of the complaint.

C. If Claims Against Apotex Inc. Are Dismissed For Lack Of Personal Jurisdiction, The Remaining Claims Against Apotex Corp. Should Also Be Dismissed For Lack Of An Indispensable Party

In the third and final portion of its motion, Apotex Corp. moved to be dismissed from this case under Fed.R.Civ.P. 19(b) in the event Apotex Inc. is dismissed for lack of personal jurisdiction (the subject of a separate motion). Plaintiffs' arguments in opposition to this portion of the motion are without merit. First, Plaintiffs fail to address the most important aspect of Apotex Corp.'s Rule 19(b) argument—that Apotex Inc. is an indispensable party under the clear language of the statute because, as explained in part II(A) above, it is Apotex Inc. that submitted the ANDA and that is the identified ANDA applicant, so the plain language of 35 U.S.C. § 271(e)(2) requires that Apotex Inc. be named as a defendant. Plaintiffs have failed to identify a single suit in which the actual ANDA applicant was not named as a party defendant in a suit

brought under Section 271(e)(2). It goes without saying that under the plain language of the statute, Apotex Inc. is an “indispensable party” in this suit.

Plaintiffs’ other various arguments are also without merit. Plaintiffs argue that this case can proceed without Apotex Inc. because Apotex Inc. “incorporate[ed] its subsidiary, Apotex USA, in Delaware and maintain[ed] that Delaware incorporation.” (Plaintiffs’ Brief p. 17.) This, however, is not true. The fact of the matter is that Apotex Corp. is not Apotex Inc.’s “subsidiary” and Apotex Inc. did not incorporate Apotex Corp. Plaintiffs’ argument based on the incorrect assumption that Apotex Inc. incorporated and owns Apotex Corp. must therefore be rejected.

Plaintiffs’ other arguments alleging that Apotex Inc. could conveniently litigate in Delaware and could assist in this litigation, or that Apotex Corp. could present evidence of patent invalidity, miss the mark. If it turns out that this Court cannot exercise personal jurisdiction over Apotex Inc., then the case cannot proceed against Apotex Corp. under Rule 19(b). Apotex Corp. is a marketing and sales entity for drugs manufactured by Apotex Inc. and other manufacturers. Apotex Inc. is the company that develops and manufactures the drugs, and thus has the scientific personnel and resources to assist its attorneys in developing the defense of patent invalidity. Apotex Inc. should not be forced to submit to the jurisdiction of this Court and participate in these proceedings simply because a different Apotex corporate entity has been named a party defendant. Instead, Apotex Inc. should be able to present evidence in support of its Paragraph IV certification for rosuvastatin calcium in a forum that can fairly exercise jurisdiction over it. Apotex Inc. has filed a declaratory judgment suit against Plaintiffs in the Middle District of Florida (Case No.08-213) and it makes more sense to transfer this case there where it can be

litigated. The fact that Apotex Inc. consented to the jurisdiction of this Court in other cases does not mean that it should be forced to litigate in this district in connection with the case at bar.

III. CONCLUSION

For the reasons stated herein and in its moving brief, Defendant Apotex Corp. respectfully requests that the Complaint against it be dismissed for failure to state a claim upon which relief can be granted; for lack of subject matter jurisdiction; and/or for failure to join an indispensable party.

Respectfully submitted,

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Dated: April 14, 2008
860176 / 32546

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on April 14, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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